UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

SKYLAR WILLIAMS, individually and on behalf of all others similarly situated, Plaintiff, v. GALDERMA LABORATORIES, L.P., Defendant.	Civil Case No. 1:24-cv-02222 Hon. Lindsay C. Jenkins

DEFENDANT GALDERMA LABORATORIES, L.P.'S REPLY IN SUPPORT OF ITS MOTION TO DISMISS

Plaintiff's Opposition provides nothing that would save her claims from express preemption under federal law. The Court should dismiss this case with prejudice.

A. PLAINTIFF'S OPPOSITION DOES NOT SAVE HER CLAIMS FROM EXPRESS PREEMPTION

Plaintiff does not dispute—and therefore concedes—that (1) FDA expressly authorizes Galderma to use BPO as the active ingredient in Differin, Mot. at 2; (2) FDA has "generally recognized" such OTC acne treatments "as safe and effective" since 2010, *id.*; (3) none of the comprehensive labeling requirements set forth in the 2020 Monograph requires Galderma to include a reference to benzene in the Differin label, *id.* at 3; and (4) her claims do not come within the scope of the federal regulations' "savings clause" for product liability claims., *id.* at 8. Accordingly, as Plaintiff herself recognizes, her claims are expressly preempted, and therefore must be dismissed, unless she has stated viable "parallel" claims under state law for misbranding or adulteration. *See* Opp'n at 5 (citing the express preemption provision of 21 U.S.C. § 379r(a)). She has not.

Plaintiff has not—and cannot—allege a cognizable misbranding claim. Plaintiff contends that federal regulations require Galderma to identify benzene as an inactive ingredient in the Differin label because the definition of "component" in 21 C.F.R. § 210 (which pertains to manufacturing regulations) "should not apply" to "component" as referenced in 21 C.F.R. § 201.66 (which pertains to labeling regulations). Opp'n at 6. Plaintiff does so in an attempt to avoid the manufacturing regulations' definition of "component" as "any ingredient ***intended for use*** in the manufacture of a drug product, including those that may not appear in such drug product." 21 C.F.R. § 210.3(a)(3) (emphasis added). If that definition applies to the labeling regulations, there can be no misbranding of Differin's label because, by Plaintiff's own allegations, benzene is not intended for use in the manufacture of BPO products at all—such products "***are not designed*** to contain benzene." Compl. ¶ 2 (emphasis added).

The court in *Barnes v. Unilever United States Inc. (Barnes II)*, 2023 WL 2456385 (N.D. Ill. Mar. 11, 2023), rejected precisely the argument Plaintiff makes here. *See* Opp'n at 6. The court cogently explained its rationale in finding that the definition of "component" applies equally to the labeling regulations:

> Both parts [21 C.F.R. § 210 and 21 C.F.R. § 201] are within the same subchapter regulating drugs, and 21 C.F.R. § 210(b)(3) provides the ***only definition*** of "component" within the subchapter. Moreover, there is evidence that rebuts the application of the *expressio unius* canon in this case. The definition of "inactive ingredient" from 21 C.F.R. § 201.66 was added after 21 C.F.R. § 210.3 was codified. In adding the "inactive ingredient" definition, the preamble to the final rule states that the definition "is identical to the definition in the agency's good manufacturing practice regulations in 21 CFR 210.3(b)(8)." Because the FDA notes that the definitions are identical, it follows that the term "component" used in both definitions was intended to have the same meaning.

Id. at *7 (emphasis added; citations omitted). As here, the plaintiff in *Barnes* contended that, had FDA intended the definition of "component" from Section 210.3 to apply to Part 201, FDA would have made that more explicit. *See* Opp'n at 6, 7 n.5; *Barnes*, 2023 WL 2456385, at *7. The court

also rejected that argument. *See id.* (noting that "the Seventh Circuit has repeatedly observed that *expressio unius* has reduced force in the context of interpreting agency administered regulations" (quotations and citation omitted)). The outcome was the same in *Truss v. Bayer Healthcare Pharmaceuticals*, No. 21 CV 9845 (VB), 2022 WL 16951538 (S.D.N.Y. Nov. 15, 2022): the court applied the Section 210 definition of "component" to 21 C.F.R. § 201.66 and dismissed claims of benzene contamination as preempted. *Id.* at *4.

Other than taking issue with the statutory interpretation in *Barnes II*, Plaintiff identifies no reason why the analysis in that case—and the outcome in both *Barnes II* and *Truss*—should not apply here with equal force. Nor does she identify any other possible definition of "component" or cite ***any*** authority that supports her position. This Court should therefore reject it.

Plaintiff's contention that she has alleged an adequate "adulteration" claim fares no better. Plaintiff fails entirely to address the fundamental defect that dooms such a claim: her entire theory of this case is premised on allegations that Differin degrades into benzene over time, not that it was contaminated during manufacturing. *See* Mot. at 10 (citing Compl. ¶¶ 40, 24-25). As Galderma noted in its Motion, the court overseeing the Zantac multidistrict litigation recently rejected this very argument—that a plaintiff can state a cognizable adulteration claim when her theory is that the product "self-adulterates." *Id*. (citing *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 20-MD-2924, 2023 WL 4765409, at *11 (S.D. Fla. July 26, 2023)). Despite the fact that *In re Zantac* is on all fours, Plaintiff ignores the case entirely and makes no attempt to explain why the Court should reach a different result here.

Plaintiff's only response to Galderma's argument that she failed to state an adulteration claim is to contend that she alleged violations of cGMPs with the required specificity. *See* Opp'n at 8-9. In support, she refers the Court to a handful of allegations of her Complaint—but those

paragraphs do not actually allege violations of cGMPs; they just list some of the standards. *See id.* at 8 (citing Compl. ¶¶ 53–55).

Plaintiff's reliance on two out-of-circuit district court opinions, *see* Opp'n at 8, is misplaced, as both cases involved factual support for the alleged cGMP violations that is missing here. In *McGee v. Johnson & Johnson*, 684 F. Supp. 3d 371 (W.D. Pa. 2023), the plaintiff averred that the defendant failed to remove "unintended particles on [plaintiff's] breast implants," which causally contributed to her injuries, in violation of a specific cGMP provision that obligates manufacturers to remove "any manufacturing material that could adversely affect [a] device's quality." *Id*. at 379, 382 (emphasis omitted). And in *In re Chantix (Varenicline) Marketing, Sales Practices & Products Liability Litigation (No. II)*, No. 22-MC-3050 (KPF), 2024 WL 2784234 (S.D.N.Y. May 28, 2024), the court found that the plaintiffs adequately alleged violations of cGMPs where the defendant had publicly acknowledged contamination in the product and voluntarily recalled it from the market. *Id*. at *2-4, *21.

McGee and *In re Chantix* are fundamentally different for an additional reason: they both involved claims that the defendant introduced a defect in the product ***during manufacturing***. *See McGee*, 684 F. Supp. 3d at 379; *In re Chantix*, 2024 WL 2784234, at *21. That fact alone distinguishes those cases from Plaintiff's allegations here, which hinge on degradation of the product ***after*** manufacturing is complete. This Court accordingly should follow the holding of *In re Zantac*, 2023 WL 4765409, at *10, and reject Plaintiff's adulteration claims. And because Plaintiff cannot cure the Complaint's defects through amendment given the disconnect between her theory of benzene formation and a claim for adulteration, dismissal should be with prejudice. *See Gonzalez-Koeneke v. West*, 791 F.3d 801, 807 (7th Cir. 2015) (district courts have "broad

discretion to deny leave to amend . . . where the amendment would be futile") (citation and quotations omitted)).

B. PLAINTIFF'S REMAINING ARGUMENTS ARE MERITLESS AND FAIL TO SAVE HER CLAIMS FROM DISMISSAL

None of Plaintiff's other arguments has merit or saves her claims from dismissal.

First, the safe harbor provisions of the Illinois Consumer Fraud Act (the "ICFA") and of other states' consumer protection laws bar Plaintiff's claims for the same reasons that her claims are preempted: controlling federal law ***expressly permits*** Galderma to sell Differin without a benzene warning. Mot. at 11 (ICFA's safe harbor provision forecloses non-personal-injury claims predicated on"[a]ctions or transactions specifically authorized by laws administered by any regulatory body or officer acting under statutory authority of this State or the United States." (quoting 815 ILCS 505/10b(1)); *id.* at 12 (citing similar safe harbor provisions of other states). In response to this point, Plaintiff argues that the safe harbor defense is not properly raised on a motion to dismiss. *See* Opp'n at 9. But the case on which she relies for that proposition recognizes that the defense is properly raised on a Rule 12 motion "when it is disclosed on the face of the complaint." *Fields v. Alcon Labs., Inc.*, No. 3:13-cv-00197 2014 WL 1041191, at *2 (S.D. Ill. Mar. 18, 2014). Courts accordingly do decide—and grant—motions to dismiss based on statutory safe harbors. *See, e.g.*, *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 942–43 (7th Cir. 2001). Plaintiff's Opposition demonstrates that the Complaint here gives rise the safe harbor defense "on its face," because she relies on the Complaint's same faulty theories of misbranding and adulteration in arguing against dismissal. *See* Opp'n at 9–10.

Because these theories fail, and because these theories form "the entire basis of Plaintiff's state law allegations" that Galderma's conduct is not authorized by law, Opp'n at 5, Plaintiff's claims fall squarely within state consumer protection safe harbor provisions. *See* Mot. at 11–12

(citing cases). Plaintiff's cases are not to the contrary. *See* Opp'n at 9; *Price v. Philip Morris, Inc.*, 848 N.E.2d 1, 35–51 (Ill. 2005) (ICFA safe harbor applied because tobacco manufacturer's labeling practices complied with Federal Trade Commission guidance); *Vanzant v. Hill's Pet Nutrition, Inc*., 934 F.3d 730, 737-38 (7th Cir. 2019) (ICFA safe harbor did not apply where defendant sold prescription pet food that FDA had not approved, which it was not authorized to do under federal law). Because it is apparent from the face of the Complaint that federal law expressly authorizes the conduct at issue, the Court should find the safe harbor provisions bar Plaintiff's claims.

Second, Plaintiff's Opposition does nothing to cure the failure to adequately allege the knowledge requirement of an omission claim under the IFCA. Plaintiff recognizes that "[t]he ICFA requires that for an omission to be actionable, it must be about a material fact that the defendant ***knew*** and concealed or failed to disclose." *See* Opp'n at 11 (emphasis added). There is not a "should have known" standard for the knowledge requirement as Plaintiff subsequently implies, *see id.*; the question is whether the defendant "***knew*** about the defect and omitted or concealed it knowing the truth." *Castaneda v. Amazon.com, Inc.*, 679 F. Supp. 3d 739, 753 (N.D. Ill. 2023) (emphasis in original). Regardless, Plaintiff fails to identify ***any*** allegation in the Complaint that supports this required claim element. On the contrary, Plaintiff directs the Court to a series of paragraphs from the Complaint that affirmatively allege the opposite—that Galderma lacked any such knowledge. *See, e.g.*, *id*. at 12 ("If Defendant had fulfilled [its] quality assurance obligations, Defendant ***would have identified*** the presence of the benzene through routine and required testing." (quoting Compl. ¶ 77) (emphasis added)). Because Plaintiff has failed to allege essential facts going to knowledge, her ICFA claim fails insofar as it is predicated on deceptive omissions. *See* Mot. at 13–14 (citing cases).

Plaintiff's cited cases, *see* Opp'n at 12–13, do not help her. *Barnes v. Unilever United States Inc. (Barnes I)*, No. 21-C-6191, 2022 WL 2915629 (July 24, 2022), did not address the question of whether knowledge was adequately pleaded. Regardless, the court there ultimately did dismiss the ICFA claim to the extent it was predicated on deceptive omissions, albeit on different grounds. *See Barnes II*, 2023 WL 2456385, at *10. And *White v. DaimlerChrysler Corp.*, 856 N.E.2d 542 (Ill. App. Ct. 2006), does not stand for the proposition that the knowledge requirement is "a question of fact to be determined by the trier of fact," as Plaintiff suggests. *See* Opp'n at 12 (quoting *White*, 856 N.E.2d at 550). As a more complete quotation makes clear, the court in that portion of its opinion was addressing a separate requirement of materiality, ***not*** knowledge. *See White*, 856 N.E.2d at 550 ("the materiality of a misrepresentation is a question of fact to be determined by the trier of fact"). *White* actually supports ***Galderma's*** position: the appellate court in that case affirmed dismissal of an ICFA claim because the plaintiff failed to allege facts that "specif[ied] how defendant knew [the] information" allegedly not disclosed. *Id.* at 549 (explaining that "it is important that the defendant be aware of the existence of the material fact ***before*** the time of the sale to the plaintiff" (emphasis added)).

Third, Plaintiff does not meaningfully respond to Galderma's argument that Plaintiff's consumer fraud multi-state subclass claim (Count III) fails because her ICFA claim fails. *See* Mot. at 14 (citing cases). Plaintiff makes no attempt to respond to or distinguish the cases that Galderma cites in its Motion, which hold that a plaintiff who fails to state a claim under the ICFA cannot "represent either an Illinois class under the ICFA or a multi-state class under the other [ ] States' consumer fraud laws." *Halperin v. Int'l Web Servs., LLC*, 123 F. Supp. 3d 999, 1009 (N.D. Ill. 2015). None of Plaintiff's cases is to the contrary, as they address an entirely separate issue—

whether a plaintiff has standing to bring claims under the laws of other states, and when that issue is appropriately addressed. *See* Opp'n at 13-14 (citing cases).

Fourth, Plaintiff admits that she failed to provide Galderma with pre-suit notice as the Massachusetts consumer protection statute requires, *see* Opp'n at 14, which should end the inquiry. It is no defense for Plaintiff to aver that she did not know that Galderma maintains a place of business in Massachusetts. *See* Opp'n at 14 (describing this as "new information"). That information is readily and publicly available through the Massachusetts Secretary of State's website. *See* Mot. Ex. A (registration application filed with the Massachusetts Secretary of State). In any event, had Plaintiff believed the pre-notice requirement did not apply to Galderma, she was required to affirmatively allege that Galderma does ***not*** maintain a place of business in Massachusetts "to show the exception to the demand letter requirement applies." *Sumner v. Mortgage Elec. Registration Sys., Inc.*, No. 11–11910, 2012 WL 3059429, at *6 (July 26, 2012). This Plaintiff did not do.

Nor did Plaintiff cite any authority that supports her position that she should be granted leave to amend her claim before she has served this required demand letter. The statutory notice requirement "is not merely a procedural nicety, but, rather, a prerequisite to suit. . . . A failure to send the required demand letter is thus fatal." *Roberts v. Crowley*, 538 F. Supp. 2d 413, 420 (D. Mass. 2008) (internal quotations and citations omitted). Massachusetts' strict adherence to this statutory pre-suit notice requirement is rooted in the twin purposes it serves: "to encourage negotiation and settlement by notifying prospective defendants of claims arising from allegedly unlawful conduct," and "to operate as a control on the amount of damages which the complainant can ultimately recover." *Spring v. Geriatric Auth. of Holyoke*, 475 N.E.2d 727, 735–36 (Mass. 1985). The case Plaintiff did cite, *Tarpey v. Crescent Ridge Dairy, Inc.*, 713 N.E.2d 975 (Mass.

1999), *see* Opp'n at 15, is inapposite. The plaintiffs there did not include a consumer protection claim in their original complaint, and sought leave to amend to add such a claim only ***after*** they served a demand letter in compliance with the statute. *Id.* at 391–92. Here, in contrast, Plaintiff requests leave to amend even though she has not served any demand letter on Galderma. Plaintiff's Massachusetts consumer protection claim must be therefore be dismissed.

Finally, Plaintiff's unjust enrichment claim (Count II) must be dismissed because that claim is based on the exact same allegations that underlie her consumer fraud claims. Plaintiff argues that "there is authority supporting . . . that unjust enrichment may in appropriate circumstances serve as a stand-alone claim under Illinois law," *see* Opp'n at 15, but she makes no effort to explain what those "appropriate circumstances" are or how they are met here. On the contrary, Plaintiff's own cited authority demonstrates that this case does ***not*** constitute such "appropriate circumstances." In *Cleary v. Philip Morris Inc*., 656 F.3d 511 (7th Cir. 2011), the Seventh Circuit explained that "if an unjust enrichment claim rests on the same improper conduct alleged in another claim, then the unjust enrichment claim will be tied to this related claim—and, of course, unjust enrichment will stand or fall with the related claim." *Id.* at 517. That is the case here: Plaintiff's unjust enrichment claim is predicated on the very same conduct that supports her consumer protection claims, *see* Compl. ¶¶ 133–38, and therefore rises and falls with those claims. Because her consumer protection claims fail, her unjust enrichment claim cannot survive.

CONCLUSION

For the foregoing reasons and for the reasons stated in its opening brief, Galderma respectfully requests that the Court dismiss Plaintiff's Complaint in its entirety.

Dated: July 1, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on July 1, 2024, the foregoing document was electronically filed with the Clerk of Court for the Northern District of Illinois through the Court's CM/ECF system, which will send a notice of electronic filing to all counsel of record.

/s/ Anand Agneshwar
Anand Agneshwar